Medical Devices and patient safety

Nordiska Tillsynskonferens 27-29.9.2017

Reykjavik

Senior Officer, PhD Tarja Vainiola

Medical Device Legislation

Medical Device directive (93/42/EEC) and Medical Device Regulation (2017/745)

1. Free movement of the medical devices within the internal market
2. High standard of quality, validated performance and safety for medical devices

Manufacturer's accountability regarding the post market surveillance is more comprehensive in the new regulation

Post-market surveillance system (article 83)
Post market surveillance report device class I (article 85)
Periodic safety update reports (article 86)
Summary of safety and performance (article 32)
Trend reporting (article 88)

The health and social care professionals **are crucial in giving the feedback to the manufacturers from devices everyday performance**

Inspected organizations

Service sector	N
Specialised medical care	15
Primary health care	3
Social care	3
Device centers for handicap	3
Dental care	3
Fertility clinic	1
In all	27

- Mostly large organizations like hospitals
- In some organization a number of different service sectors existed
  - Nursing care
  - Home care
  - Dental care

Topics evaluated within inspections

- The vigilance process
- Medical device user training
- The maintenance of medical devices
- Traceability of the medical devices
- Nomination and liability of the responsible person

Main Results

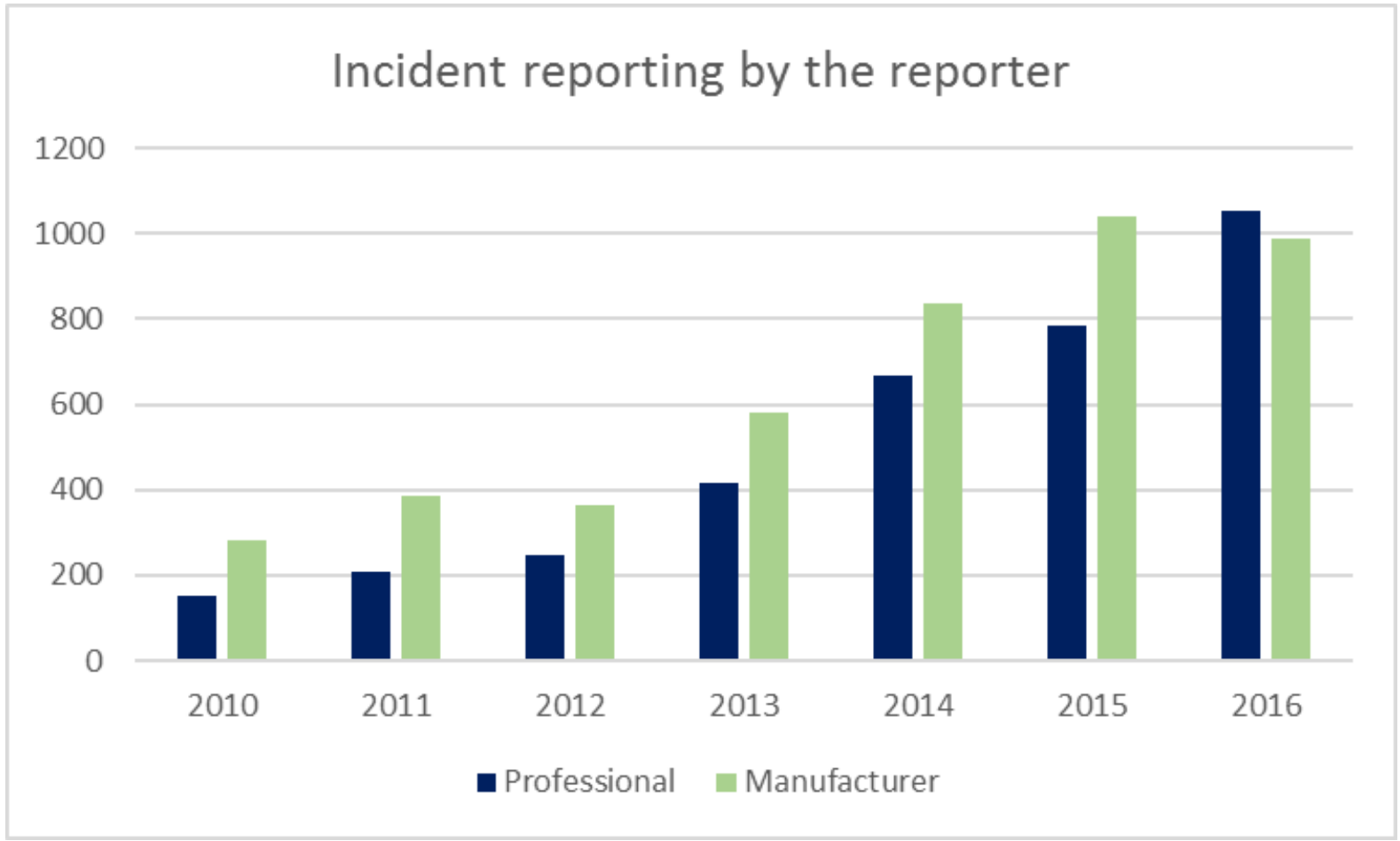
Only one organisation fullfilled the obligations on the moderate level

Shortcoming	N
Vigilance process	23
Traceability	15
Maintanance	14
Training	12
Responsible person	7
In all	71

Challenge I – Vigilance reporting

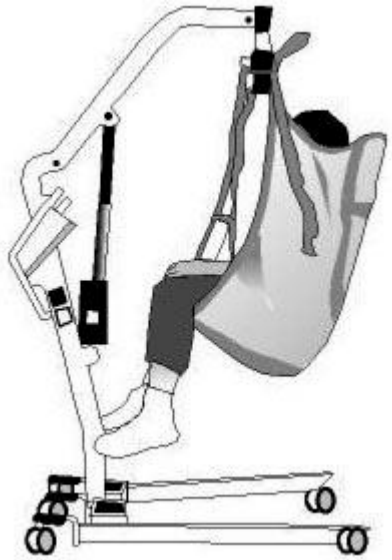
- **The under reporting of the vigilance issues is a challenge for the medical device safety**

- **The causes of under reporting in Finland**
  - Professional are not aware about the vigilance reports and scope of them
    - Vigilance reports regarding the long term performance of the devices is almost lacking
  - The organizations has no guidance on the vigilance process
    - The management of the involved device
    - The manufacturer's contact information is lacking
    - The responsibility issues are defined incompletely


Incident reporting by the reporter
1200
1000
800
600
400
200
0
2010
2011
2012
2013
2014
2015
2016
Professional
Manufacturer

Challenge II –Assisted Living Residence and Home Health Care

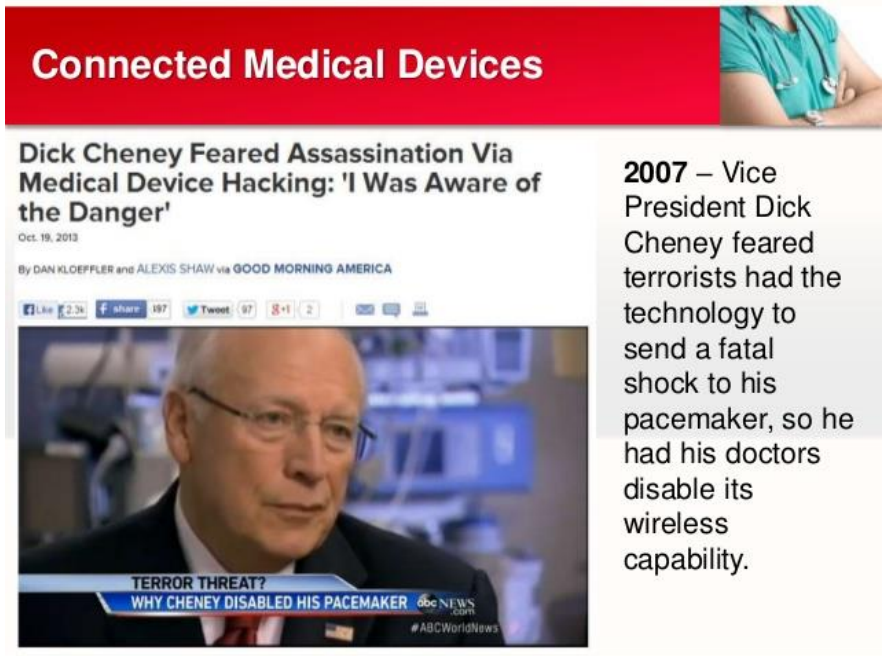
- Number of different type of medical devices are used in nonclinical environments
  - E.g tracheotomy care, specialized mattress, apnea monitor, infusion pumps, suction machine, oxygen concentrator, test Kits
  - Varied population of users
    - caregivers, social workers, care aides, lay caregivers, laypersons
  - The environment is suitable for the usage of the medical device
- **Define policy for**
  - Users training
  - Availability of the instruction for use
  - Maintenance
  - Traceability
  - Vigilance reports
    - users may not have access to reporting systems or the information is limited



Challenge III – Remote Monitoring

Remote monitoring is available for treatment and follow-up of many diseases

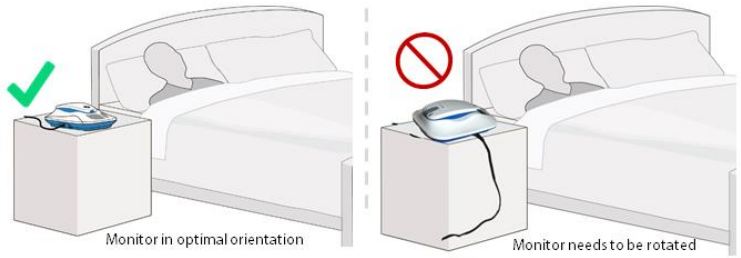
- diabetes, asthma, sleep apnea, heart failure etc.



Hack attack on a hospital IT system highlights the risk of still running Windows XP
January 20, 2016 7.22pm GMT

•Lily Hay Newman, 03.02.17
Medical Devices Are the Next Security Nightmare
Johnson & Johnson warned customers about a security bug in one of its insulin pumps last fall. There's a need to protect patients, so that attackers can't hack an insulin pump to administer a fatal dose.

- **Thing to be taken into account when obtaining remote monitoring systems**
  - Data security
  - Data transmission
    - the data accuracy
  - Data storage
    - In cloud computing or integrated to the patient information system
  - The device usability
    - Patients age



Software Update via Internet

Software update via internet

- Healthcare professionals are not aware about the updates

Field Safety Corrective Action (FA719) by Medtronic

- Concerns The MyCareLink™ Patient Monitor
  - Abnormal heart rhythm data is automatically sent to hospital
- Software transmission and updating failed
- Corrective action: Replacement devices
- Transmission problems may lead to delayed medical intervention.

IT experts should be involved into the implementation process